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510(k) Summary
for the Omnyx, LLC.
Omnyx Manual Read of the Digital HER2 Application

1. SUBMITTER/510(K) HOLDER

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3. DEVICE NAME

Proprietary Name:	Omnyx Manual Read of the Digital HER2 Application
Common/Usual Name:	Digital Pathology Device
Classification:	Class II
Product Code:	OEO (automated digital image manual interpretation microscope)

4. PREDICATE DEVICES

- Aperio ScanScope XT System (K071671)
- Virtuoso™ IHC HER2 (K111543)

5. DEVICE DESCRIPTION

The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended to aid pathology professionals in creating, managing, storing, annotating, measuring, and viewing digital Whole Slide Images (WSI) from formalin-fixed, paraffin-embedded (FFPE) tissue sections stained with the Dako HercepTest™.

The system is composed of the following components:

- **VL4 Scanner:** A hardware device that captures and compresses bright field images of tissue samples.
- **Data and Workflow Infrastructure:** A set of networked applications which enables case data entry, acquisition, indexing, storage and acceptance of digital images, workflow management, and retrieval of case and image data.
- **Histology Workstation:** The application which permits the histologist to review or enter case data and check quality of scanned images.
- **Pathology Workstation:** The application which allows the pathologist to retrieve case data and review and annotate slide images.

Hardware:

The Omnyx™ VL4 scanner is an automated imaging system that can be loaded with up to 4 slides at a time. The VL4 Scanner outputs its images and metadata to the Omnyx Digital Archive, which receives and stores the images and data.

Software:

The Omnyx software is composed of 1) the VL4 scanner software which performs tissue identification, scan planning, focusing, image acquisition, stitching and compression of digital slide images and sends them to the Digital Archive and 2) the DPS software that manages the Histologist and Pathologist workstation functions, image viewer, workflow service, database, interface engine, APLIS service, digital archive, image store and the administrator client application.

Principles of Operation:

FFPE tissue sections are stained with the Dako HercepTest™ according to the package insert. Slides are then scanned and digitized using the Omnyx VL4 Scanner. Whole slide images are transferred automatically to the Omnyx Digital Archive (DA) where they are indexed and stored. The Workflow Server contains patient information. These files are then accessed using the Histology Workstation or the Pathologist Workstation. The Histology Workstation is used by histologists or other lab professionals to perform quality checks on scanned slides, confirm that IHC slides/case associations are correct and order re-cuts and re-stains. It also enables the histologist to enter case data manually. The Pathologist Workstation enables the pathologist to flag significant cases and regions of interest. It also allows the pathologist to review the digital HercepTest™ IHC whole slide image (WSI) via the Omnyx Image Viewer and is used by the pathologist for functions such as annotating images and making measurements.

6. INDICATIONS FOR USE/ INTENDED USE

The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended for in vitro diagnostic use as an aid to pathology professionals for creating, managing, storing, annotating, measuring, and viewing digital Whole Slide Images (WSI) from formalin-fixed, paraffin-embedded (FFPE) tissue sections stained with the Dako HercepTest™.

The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in digital images of FFPE breast cancer tissue immunohistochemically stained with the Dako HercepTest™ and viewed on a computer monitor.

The Dako HercepTest™ is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The following table summarizes the similarities and differences between the Omnyx Manual Read of the Digital HER2 Application and the predicate devices Aperio ScanScope XT System and Virtuoso™ IHC HER2.

Similarities/Differences of Omnyx Manual Read of the Digital HER2 Application with Predicate Devices

	Proposed Device	Predicate	Predicate
Comparators	**Omnyx Manual Read of the Digital HER2 Application**	**Aperio ScanScope XT System (K071671)**	**Virtuoso™ IHC HER2 (K111543)**
Intended use	The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended for in vitro diagnostic use as an aid to pathology professionals for creating, receiving, managing, storing, annotating, measuring, and viewing digital Whole Slide Images (WSI) from formalin-fixed, paraffin-embedded (FFPE) tissue sections stained with the Dako HercepTest™. The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in digital images of FFPE breast cancer tissue immunohistochemically stained with the Dako HercepTest™ and viewed on a computer monitor. Dako HercepTest™ is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.	The ScanScope system is an automated digital slide creation, management, viewing and analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape. The IHC HER2 Manual Read of a Digital Slide application is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded normal and neoplastic tissue immunohistochemically stained for HER-2 receptors on a computer monitor. HER2 results are indicated for use as an aid in the management, prognosis and prediction of therapy outcomes in breast cancer. The IHC HER2 Manual Read of a Digital Slide application is intended for use as an accessory to the Dako HercepTest™ to aid in the detection and semi-quantitative measurement of HER2/neu (c-ebB-2) in formalin-fixed, paraffin-embedded normal and neoplastic tissue immunohistochemically stained for HER-2 receptors on a computer monitor. When used with the Dako HercepTest, it is	This device is intended for in vitro (IVD) use. The Virtuoso System provides automated digital slide creation, management, analysis, and viewing. It is intended for IVD use as an aid to the pathologist in the display, detection, counting, review and classification of tissues and cells of clinical interest based on particular morphology, color, intensity, size, pattern and shape. The Virtuoso™ System for IHC HER2 (4B5) is for digital read and image analysis applications. This particular Virtuoso system is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2 protein in formalin-fixed, paraffin-embedded normal and neoplastic tissue. This device is an accessory to the Ventana Medical Systems, Inc. PATHWAY® anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody. The PATHWAY® anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered. Note: The IHC HER2 (4B5) Digital Read and Image Analysis applications are adjunctive computer-assisted methodologies for the qualified pathologist in the acquisition and measurement of images from microscope glass slides of breast cancer specimens stained for the presence of

Comparators	Proposed Device Omnyx Manual Read of the Digital HER2 Application	Predicate Aperio ScanScope XT System (K071671)	Predicate Virtuoso™ IHC HER2 (K111543)
		indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered. Note: The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.	HER-2/neu receptor protein. The pathologist should verify agreement with the Image Analysis software application score. The accuracy of the test results depends on the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the PATHWAY® anti-HER-2.neu (4B5) Rabbit Monoclonal Primary Antibody assay used to assure the validity of the iScan System for IHC HER2 Digital Read and Image Analysis scores. The actual correlation of PATHWAY® anti-HER-2/neu (4B5) to clinical outcome has not been established.
Specimen Type	Formalin-fixed, paraffin-embedded normal and neoplastic tissue immunohistochemically stained	Same	Same
Device Components	Automated digital slide scanner, computer, color monitor, keyboard, and digital pathology information management software	Automated digital microscope slide scanner, computer, color monitor, keyboard and digital pathology information management software	BioImagene (now Ventana) iScan slide scanner, computer, color monitor, proprietary software for HER2 (4B5)
Image Acquisition	Tile sensor technology	Line scanning technology	Same
Light Source	LED	Tungsten light	Same
Primary Antibody (Assay) Reagent	Dako Reagents for HER2 (HercepTest™)	Same	Ventana PATHWAY HER2 (4B5) (P990081 S003)
Interpretation (Modes of Operation)	Interpretation is performed by the pathologist (Manual digital read)	Same	Manual and Automated

8. SUMMARY OF NON-CLINICAL AND CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

CLINICAL COMPARISON TO MANUAL MICROSCOPY

Each of the four (4) pathologists read 200 breast cancer cases, comprising of both the controls and specimen slides stained with the Dako HercepTest™, using a conventional manual microscope (MM) and the Omnyx™ IDP (M-WSI), separated by at least a 2 week washout period. Three (3) VL4 scanners were installed in separate laboratories, with each scanner associated with a different scanner technician. Each pathologist reviewed WSIs obtained from different VL4 scanners, although two (2) of the pathologists received WSIs from the same VL4 scanner. The pairwise percent agreement between all pathologist on both MM and M-WSI modalities (inter-reader/intra-modality) was determined for both binned (0/1+ = neg; 1+/2+ = pos) and trichotomous (0/1+, 2+, 3+) score categories. Furthermore, in order to determine how well each pathologist could recapitulate a slide score for each slide when read on each modality, an analysis of the percent agreement between MM vs. M-WSI (inter-modality/intra-reader) for each pathologist was determined.

Inter-Reader/ Intra-Modality (MM)		Pathologist 2				Pathologist 3				Pathologist 4				Pathologist 3				Pathologist 4				Pathologist 4			
		0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+
Pathologist 1	0	46	9	1	0	50	6	0	0	46	9	0	0												
	1+	7	18	8	1	7	22	6	0	1	30	3	0												
	2+	0	7	28	4	1	6	32	0	0	23	15	0												
	3+	1	0	6	63	0	0	11	59	0	0	12	56												
Pathologist 2	0													50	3	1	0	43	9	1	0				
	1+													7	23	4	0	3	30	2	0				
	2+													1	7	34	1	1	22	19	0				
	3+													0	0	10	58	0	1	8	56				
Pathologist 3	0																					46	11	0	0
	1+																					1	32	1	0
	2+																					0	19	26	2
	3+																					0	0	3	54
% Agreement (95% CI) (Trichotomous)		85.9% (80%-90%)				88.0% (83%-92%)				80.5% (74%-85%)				87.9% (83%-92%)				82.1% (76%-87%)				87.2% (82%-91%)			

Inter-Reader/Intra-Modality on Glass (MM) between four (4) pathologists - Trichotomous score categories

Inter-Reader/ Intra-Modality (M-WSI)		Pathologist 2				Pathologist 3				Pathologist 4				Pathologist 3				Pathologist 4				Pathologist 4			
		0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+	0+	1+	2+	3+
Pathologist 1	0	48	6	0	0	28	21	5	0	29	22	0	0												
	1+	4	22	11	1	1	11	23	3	0	34	3	0												
	2+	0	7	26	6	1	0	19	19	1	20	16	1												
	3+	1	0	7	60	0	0	2	66	1	0	7	54												
Pathologist 2	0													28	20	4	1	28	21	0	1				
	1+													2	12	20	1	1	33	0	0				
	2+													0	0	22	22	2	19	20	0				
	3+													0	0	3	64	0	3	6	54				
Pathologist 3	0																					25	3	0	0
	1+																					4	26	0	0
	2+																					1	40	8	0
	3+																					1	7	18	55
% Agreement (95% CI) (Trichotomous)		83.4% (78%-88%)				73.4% (67%-79%)				82.4% (76%-87%)				74.4% (68%-80%)				83.5% (78%-88%)				64.4% (57%-71%)			

Inter-Reader/Intra-Modality on Digital (M-WSI) between four (4) pathologists – Trichotomous score categories

To calculate the negative & positive percent agreements, the 4x4 binary agreements are binned into a 2x2 table with 0/1+ (Negative) combined and 2+/3+ (Positive) combined. Since neither pathologist can be considered a reference in each pairwise reader comparison, analysis for negative and positive score categories is provided as Average Negative Agreement (ANA) and Average Positive Agreement (APA).

Inter-Reader/ Intra-Modality (MM)		Pathologist 2		Pathologist 3		Pathologist 4		Pathologist 3		Pathologist 4		Pathologist 4	
		Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Pathologist 1	Neg	80	10	85	6	86	3						
	Pos	8	101	7	102	23	83						
Pathologist 2	Neg							83	5	85	3		
	Pos							8	103	24	83		
Pathologist 3	Neg											90	1
	Pos											19	85
Overall Percent Agreement (95% CI)		91.0% (86%-94%)		93.5% (89%-96%)		86.7% (81%-91%)		93.5% (89%-96%)		86.2% (81%-90%)		89.7% (85%-93%)	
Average Positive Agreement (95% CI)		89.9% (85%-94%)		92.9% (88%-96%)		86.9% (81%-91%)		92.7% (88%-96%)		86.3% (81%-90%)		90.0% (85%-93%)	
Average Negative Agreement (95% CI)		91.8% (87%-95%)		94.0% (90%-96%)		86.5% (81%-91%)		94.1% (90%-96%)		86.0% (80%-90%)		89.5% (84%-93%)	

Inter-Reader/Intra-Modality on Glass (MM) between four (4) pathologists – Binary score categories

Inter-Reader/ Intra-Modality (M-WSI)		Pathologist 2		Pathologist 3		Pathologist 4		Pathologist 3		Pathologist 4		Pathologist 4	
		Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Pathologist 1	Neg	80	12	61	31	85	3						
	Pos	8	99	1	106	22	78						
Pathologist 2	Neg							62	26	83	1		
	Pos							0	111	24	80		
Pathologist 3	Neg											58	0
	Pos											49	81
Overall Percent Agreement (95% CI)		89.9% (85%-93%)		83.9% (78%-88%)		86.7% (81%-91%)		86.9% (82%-91%)		86.7% (81%-91%)		73.9% (67%-80%)	
Average Positive Agreement (95% CI)		88.9% (83%-93%)		79.2% (72%-85%)		87.2% (82%-91%)		82.7% (76%-88%)		86.9% (81%-91%)		70.3% (63%-77%)	
Average Negative Agreement (95% CI)		90.8% (86%-94%)		86.9% (82%-91%)		86.2% (80%-90%)		89.5% (85%-93%)		86.5% (81%-91%)		76.8% (71%-82%)	

Inter-Reader/Intra-Modality on Digital (M-WSI) between four (4) pathologists – Binary score categories

The inter-modality/intra-reader agreement results evaluating glass vs. digital (MM vs. M-WSI) for all four (4) pathologists are shown below. The washout period between the glass and digital reads was a minimum of 2 weeks.

Inter-Modality/Intra-Reader (MM vs. M-WSI)		Glass (MM)															
		Pathologist 1				Pathologist 2				Pathologist 3				Pathologist 4			
		0	1+	2+	3+	0	1+	2+	3+	0	1+	2+	3+	0	1+	2+	3+
Digital (M-WSI)	0	50	4	0	0	47	3	2	1	29	1	0	0	29	0	2	0
	1+	6	26	6	0	5	25	5	0	25	7	0	0	16	54	5	0
	2+	0	5	32	2	0	7	30	7	4	24	21	0	0	6	20	0
	3+	0	0	1	67	2	0	6	60	0	2	28	58	0	0	3	52
% Agreement (95% CI) (Trichotomous)		93.0% (89%-96%)				85.0% (79%-89%)				70.9% (64%-77%)				91.4% (87%-95%)			

Intra-Reader/Inter-Modality comparing agreement between glass and digital (MM vs. M- WSI) for each of the four (4) pathologists - Trichotomous score categories

To calculate the negative & positive percent agreements, the 4x4 binary agreement tables are binned into a 2x2 table with 0/1+ (Negative) combined and 2+/3+ (Positive) combined. Since the glass scores for each pathologist is used as their respective reference, the analysis is provided as Negative Percent Agreement (NPA) and Positive Percent Agreement (PPA), with the glass reads as the imperfect reference.

Inter-Modality/Intra-Reader (MM vs. M-WSI)		Glass (MM)							
		Pathologist 1		Pathologist 2		Pathologist 3		Pathologist 4	
		Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Digital (M-WSI)	Neg	86	8	80	8	62	0	99	7
	Pos	5	75	9	103	30	107	6	75
Overall Percent Agreement (95% CI)		92.5% (88%-96%)		91.5% (87%-95%)		89.4% (79%-89%)		93.0% (88%-96%)	
Negative Percent Agreement (95% CI)		94.5% (88%-98%)		89.9% (82%-95%)		67.4% (57%-76%)		94.3% (88%-97%)	
Positive Percent Agreement (95% CI)		90.4% (82%-95%)		92.8% (86%-96%)		100% (97%-100%)		91.5% (83%-96%)	

Intra-Reader/Inter-Modality comparing agreement between glass and digital (MM vs. M- WSI) for each of the four (4) pathologists – Binary score categories

The pairwise inter-reader/intra-modality percent agreements do not differ significantly between MM and M-WSI. Additionally, there are high percent agreements between MM and M-WSI for each pathologist when examined by binary or trichotomous score category.

PRECISION & REPRODUCIBILITY

INTRA-READER/INTER-DAY

In order to compare the intra-reader variability on digital M-WSI, three (3) pathologist performed three (3) independent readings of a set of the HercepTest™ stained slides (n=40) using the M-WSI modality. Each of the three reads was separated by a minimum one week wash out, with the inclusion of wildcards. The results are presented as both trichotomous and binary analysis, with additional negative and positive percent agreements (NPA and PPA).

Intra-Reader/Inter-Day (M-WSI)		Read 2				Read 3				Read 3			
		0	1+	2+	3+	0	1+	2+	3+	0	1+	2+	3+
Read 1	0	6	3	1	0	8	2	0	0				
	1+	0	3	11	0	0	8	6	0				
	2+	0	0	4	3	0	0	4	3				
	3+	0	0	0	9	0	0	0	9				
Read 2	1									6	0	0	0
	1+									2	4	0	0
	2+									0	6	10	0
	3+									0	0	0	12
% Agreement (95% CI) (Trichotomous)		62.5% (47%-76%)				77.5% (62%-88%)				85.0% (71%-93%)			

Intra-Reader/Inter-Day on Digital (MM) for Pathologist 1 – Trichotomous score categories

Intra-Reader/Inter-Day (M-WSI) Pathologist 1		Read 2		Read 3		Read 3	
		Neg	Pos	Neg	Pos	Neg	Pos
Read 1	Neg	12	12	18	6		
	Pos	0	16	0	16		
Read 2	Neg					12	0
	Pos					6	22
Overall % Agreement (95% CI)		70.0% (55%-82%)		85.0% (71%-93%)		85.0% (71%-93%)	
Negative % Agreement (95% CI)		66.7% (50%-80%)		85.7% (72%-93%)		80.0% (63%-90%)	
Positive % Agreement (95% CI)		72.7% (58%-84%)		84.2% (70%-93%)		88.0% (76%-94%)	

Intra-Reader/Inter-Day on Digital (MM) for Pathologist 1 - Binary score categories

Intra-Reader/Inter-Day (M-WSI)		Read 2				Read 3				Read 3			
		0	1+	2+	3+	0	1+	2+	3+	0	1+	2+	3+
Read 1	0	8	0	0	0	8	0	0	0				
	1+	0	8	1	0	1	8	0	0				
	2+	0	1	10	0	0	1	10	0				
	3+	0	0	0	12	0	0	0	12				
Read 2	1									8	0	0	0
	1+									1	8	0	0
	2+									0	1	10	0
	3+									0	0	0	12
% Agreement (95% CI) (Trichotomous)		95.0% (83%-99%)				97.5% (87%-100%)				97.5% (87%-100%)			

Intra-Reader/Inter-Day on Digital (MM) for Pathologist 2 - Trichotomous score categories

Intra-Reader/Inter-Day (M-WSI) Pathologist 2		Read 2		Read 3		Read 3	
		Neg	Pos	Neg	Pos	Neg	Pos
Read 1	Neg	16	1	17	0		
	Pos	1	22	1	22		
Read 2	Neg					17	0
	Pos					1	22
Overall % Agreement (95% CI)		95.0% (83%-99%)		97.5% (87%-100%)		97.5% (87%-100%)	
Negative % Agreement (95% CI)		94.1% (81%-98%)		97.1% (85%-99%)		97.1% (85%-99%)	
Positive % Agreement (95% CI)		95.7% (85%-99%)		97.8% (88%-100%)		97.8% (88%-100%)	

Intra-Reader/Inter-Day on Digital (MM) for Pathologist 2 - Binary score categories

Intra-Reader/Inter-Day (M-WSI)		Read 2				Read 3				Read 3			
		0	1+	2+	3+	0	1+	2+	3+	0	1+	2+	3+
Read 1	0	5	0	0	0	5	0	0	0				
	1+	3	3	0	0	1	5	0	0				
	2+	0	1	15	3	0	0	15	4				
	3+	0	0	0	10	0	0	0	10				
Read 2	1									5	3	0	0
	1+									1	2	1	0
	2+									0	0	14	1
	3+									0	0	0	13
% Agreement (95% CI) (Trichotomous)		90.0% (77%-96%)				90.0% (77%-96%)				95.0% (83%-99%)			

Intra-Reader/Inter-Day on Digital (MM) for Pathologist 3 - Trichotomous score categories

Intra-Reader/Inter-Day (M-WSI) Pathologist 3		Read 2		Read 3		Read 3	
		Neg	Pos	Neg	Pos	Neg	Pos
Read 1	Neg	11	0	11	0		
	Pos	1	28	0	29		
Read 2	Neg					11	1
	Pos					0	28
Overall % Agreement (95% CI)		97.5% (87%-100%)		100.0% (91%-100%)		97.5% (87%-100%)	
Negative % Agreement (95% CI)		95.7% (79%-99%)		100.0% (85%-100%)		95.7% (79%-99%)	
Positive % Agreement (95% CI)		98.2% (91%-100%)		100.0% (94%-100%)		98.2% (91%-100%)	

Intra-Reader/Inter-Day on Digital (MM) for Pathologist 3 - Binary score categories

INTER-SCANNER/INTRA-READER

To determine the scanner-to-scanner variability, we performed a subjective inter-scanner study. A set of 80 regions of interest (ROIs) extracted from WSIs of forty (40) HercepTest™ slides, with even distribution of the score categories, were obtained from three (3) different scanners. The three scanners were located in three different laboratory locations within GE Healthcare and operated by three independent operators. Each read session (for each scanner) was separated by a minimum of 1 week washout period, with the inclusion of wildcard ROIs during each scanner's ROI reads. All ROIs were manually scored by a single pathologist based on the Dako HercepTest™ scoring guidelines. Percent agreement between each of the scanner pairs were determined based on the ROI scores.

Inter-Scanner/Intra-Reader		Scanner 2				Scanner 3				Scanner 3			
		0	1+	2+	3+	0	1+	2+	3+	0	1+	2+	3+
Scanner 1	0	25	2	0	0	26	1	0	0				
	1+	3	11	1	0	3	10	2	0				
	2+	0	0	19	3	0	1	15	6				
	3+	0	0	0	16	0	0	0	16				
Scanner 2	1									26	2	0	0
	1+									3	9	1	0
	2+									0	1	15	4
	3+									0	0	1	18
% Agreement (95% CI) (Trichotomous)		95.0% (88%-98%)				88.8% (80%-94%)				91.3% (83%-96%)			

Inter-Scanner/Intra-Reader Agreement using Region of Interests (ROIs) obtained from 3 VL4 scanners and scored by a single pathologist (Pathologist 2) - Trichotomous score categories

When analyzed trichotomously (0/1+, 2+ and 3+), the inter-scanner/intra-reader variability had high percent agreement across all pairwise scanner comparisons. This data indicates a very high reproducibility among scanners and further suggests that M-WSI inter-scanner variability is primarily due to the subjectivity of score interpretation of the readers and not by scanner to scanner variability.

9. SUMMARY OF OTHER INFORMATION

This submission included a comparison of intended use statements, proposed product labeling, software validation and summary information and labeling on predicate devices.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information provided in this 510(k), Omnyx believes that the proposed Omnyx Manual Read of the Digital HER2 Application is substantially equivalent to the previously cleared predicate products. The proposed device raises no new issues of safety and effectiveness. The non-clinical and clinical testing performed demonstrates that the proposed device met all the specifications and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 1, 2014

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62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K131140
Trade/Device Name: OmnyxManual Read of the Digital HER2 Application
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: II
Product Code: OEO
Dated: March 12, 2014
Received: March 13, 2014

Dear Dr. Radcliffe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip -S

for

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131140

Device Name
Omnyx Manual Read of the Digital HER2 Application

Indications for Use *(Describe)*
The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended for in vitro diagnostic use as an aid to pathology professionals for creating, managing, storing, annotating, measuring, and viewing digital Whole Slide Images (WSI) from formalin-fixed, paraffin-embedded (FFPE) tissue sections stained with the Dako HercepTest™.

The Omnyx Manual Read of the Digital HER2 Application on the Omnyx IDP System is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in digital images of FFPE breast cancer tissue immunohistochemically stained with the Dako HercepTest™ and viewed on a computer monitor.

The Dako HercepTest™ is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yun-fu Hu -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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